

### REMARKS

Claims 1-34 are in the case. Claims 1, 2 and 16 have been amended, and claims 18-34 have been added. Claims 3-15 and 17 remain unchanged.

Claims 1-9 and 15-17 have been rejected as being anticipated by Bernstein et al (U.S. Patent 5,824,268). Dependent claims 10-13 have been rejected as being unpatentable over Bernstein et al. in view of Kang et al (U.S. Patent 6,027,943), and dependent claims 8 and 14 have been rejected as being unpatentable over Bernstein et al. in view of Chandler (US Patent 6,165,416).

In one aspect, recited in claims 1 and 2, Applicants' invention features a device for use in the collection and testing of a sample, including a sample collection device and a housing having an internal recess. The housing is adapted to receive at least a portion of the sample collection device in the internal recess, and to shield a sample collected on the sample collection device. The housing is also adapted to receive an insertable testing element so that, on insertion of the testing element into the housing, the testing element is in liquid-conductive communication with a sample collected on the sample collection device.

Because the housing is adapted to receive at least a portion of the sample collection device in the internal recess and to shield the sample, a sample can be collected in one location and/or at one time, and tested at a different location and/or a later time by inserting the insertable testing element at that location/time (see, e.g., p. 4, lines 17-20, p. 5, lines 3-4, p. 6, lines 19-25, and p. 11, lines 23-25 of Applicants' specification).

Accordingly, sample collection may be performed at locations where laboratory facilities and skilled personnel are unavailable (see, e.g., Applicants' specification, p. 8, lines 8-10 and the paragraph bridging pp. 8 and 9.) For example, in some cases a patient may obtain a sample in his or her home, and then send the sample to a remote location for centralized test development.

The device described in the Bernstein reference is fundamentally different from the device of Applicants' invention. The Bernstein device is a simple "Point of Care" testing device, having a test strip to which a sample would be applied immediately after the sample was taken.

Thus, the Bernstein device is similar to the devices discussed in the Background section of Applicants' specification at page 4.

Bernstein does not teach or suggest a testing device that includes an internal recess into which a sample collection device can be inserted. Instead, in the Bernstein device, a test strip is sealed within an internal recess in the housing, and the sample collection device 10 is applied to a window 34 in the housing cover. The sample collecting device 10 of Bernstein's test kit cannot be received and shielded by the sealed recess in Bernstein's housing, but can only be applied externally to window 34. As a result of this structural difference, the Bernstein device cannot be used to store and transport a sample that will be tested at a different time and/or location.

While the Examiner characterizes the sample-receiving zone of Bernstein's test strip as being analogous to the claimed sample collection device, Applicants respectfully submit that this characterization is improper. Bernstein's test kit includes, in addition to his test strip, a "sample collecting device 10." Applicants' claim recites, in addition to the sample collection device, an "insertable testing element," which, insofar as it is used to perform a testing function, is analogous to Bernstein's test strip. Thus, a more reasonable interpretation would be that Bernstein's sample collecting device 10 is generally analogous to Applicants' claimed sample collection device, and Bernstein's test strip to generally analogous to Applicant's insertable testing element.

Reading Bernstein in this manner, as discussed above Bernstein clearly does not teach or suggest a device as recited in claims 1 and 2.

In another aspect, recited in amended claim 16, Applicants' invention features a method for the identification of an analyte of interest in a sample, including: (a) collecting a sample on a sample collection device; (b) inserting at least a sample-carrying portion of said sample collection device into an internal recess within a housing of a testing device, the housing being adapted to receive the sample-carrying portion of the sample collection device in the internal recess and to shield the sample; and (c) subsequently inserting an insertable testing element into the housing such that the testing element is in liquid-conductive communication with the sample.

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Serial No.: 09/936,452  
Filed : September 12, 2001  
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Attorney's Docket No.: 13521-002001  
2453801/PP9157/99-JMS

As discussed above, Bernstein does not teach or suggest inserting a sample-carrying portion of a sample collection device into a recess that is adapted to receive and shield the sample. Nor does Bernstein teach or remotely suggest, after doing so, subsequently inserting an insertable testing element into the housing. Thus, the claimed method, like the claimed device, is fundamentally different from that of Bernstein.


The secondary references cited by the Examiner do not supply what is lacking in the Bernstein reference. Thus, claims 8 and 10-14 are patentable for at least the reasons discussed above with respect to claims 1 and 2.

Please apply any charges or credits to deposit account 06-1050, referencing attorney docket number 13521-002001.

Respectfully submitted,

Date:

Sept. 25, 2003

  
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